DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO ATTENTION OF:
MCMR-UMZ (70)

DEC 17 '97

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Assignment of Human Use Study Monitoring Responsibility for Investigational Medical Products

1. Effective immediately, I am directing that *all* Food and Drug Administration regulated human use studies being performed under Investigational New Drug (IND)or Investigational Device Exemption (IDE) protocols for The Surgeon General (TSG) be monitored for compliance by the U.S. Army Medical Materiel Development Activity. The studies will conform to the provisions of 21 CFR and Office of The Surgeon General Reg 15-2, AR 70-25, and AR 40-7. This monitoring will include all early development human use (tech base) protocols, the Special Immunization Program and Advanced Development protocols. The USAMMDA has full monitoring responsibility and accountability.

2. All IND and IDE clinical studies sponsored by TSG must have appropriate administrative policies, procedures and resources applied to achieve appropriate compliance with regulations. Studies that do not comply will be designated for clinical hold until corrective actions are taken, or they will be terminated.

3. The Deputy Chief of Staff for Regulatory Compliance and Quality (RCQ) has USAMRMC Headquarters accountability and oversight responsibility for all Command IND activities. Regulatory Compliance and Quality will develop policies to ensure overall Command compliance with regulations relating to human use IND and IDE studies.

4. All Headquarters elements and subordinate commands are directed to support the USAMMDA and RCQ in this exceedingly important mission.

RUSS ZAJTCHUK
Brigadier General, MC
Commanding

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